UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC.,

Plaintiff,

- against -

CORERX, INC.,

Defendant.

21-cv-10656 (JGK)

MEMORANDUM OPINION AND ORDER

JOHN G. KOELTL, District Judge:

The plaintiff, Bionpharma Inc. ("Bionpharma"), brought this action against the defendant, CoreRx, Inc. ("CoreRx"), for breach of contract and declaratory judgment. On January 27, 2022, the Court granted the plaintiff's request for a preliminary injunction pursuant to Federal Rule of Civil Procedure 65, compelling the defendant to supply the plaintiff with enalapril maleate oral solution in accordance with the parties' Master Manufacturing Supply Agreement (the "Agreement"). See Bionpharma Inc. v. CoreRx, Inc., 2022 WL 246742 (S.D.N.Y. Jan. 27, 2022) (hereinafter, "Opinion & Order"). The preliminary injunction went into effect on February 4, 2022. ECF No. 79.

Before the Court are four motions: (1) a motion by CoreRx to (a) stay the preliminary injunction pending the resolution of CoreRx's appeal from this Court's Opinion & Order, or (b) stay the preliminary injunction temporarily for a brief period to allow the court of appeals to consider a stay pending appeal,

pursuant to Federal Rule of Civil Procedure 62; (2) a motion by CoreRx to require Bionpharma to post security to maintain the preliminary injunction pursuant to Federal Rule of Civil Procedure 65(c); (3) a motion by Azurity Pharmaceuticals, Inc. ("Azurity") to intervene for the limited purpose of appealing this Court's Opinion & Order pursuant to either Federal Rule of Civil Procedure 24(a) or (b); and (4) a motion by Azurity to supplement the record. For the following reasons, (1) CoreRx's motion for a stay pending appeal is **denied**, but its request for an interim stay is **granted**; (2) CoreRx's motion requiring Bionpharma to post a security bond is **granted**; (3) Azurity's motion to intervene as of right is **denied**, but its alternative request to intervene permissively is **granted**; and (4) Azurity's motion to supplement the record is **denied**.

I.

The Court assumes general familiarity with the facts of this case, which are set forth in the Opinion & Order. 2022 WL 246742, at *1-4.

In brief, Bionpharma is a generic pharmaceutical company that sells an enalapril maleate oral solution product (the "Product") that is marketed as a generic version of the branded drug "Epaned." Id. at *1. Epaned is owned by Azurity, a pharmaceutical company that is a competitor to Bionpharma. Id. Azurity and its predecessor company have initiated a flurry of

patent litigation against Bionpharma for alleged violations of the Epaned patents since August 2018, when Bionpharma submitted an Abbreviated New Drug Application to the Federal Drug Administration. Id. at *1-2. So far, none of these lawsuits have been successful. Id.

In November 2020, Bionpharma and CoreRx, a pharmaceutical Contract Development Manufacturing Organization, entered into the Agreement, whereby CoreRx agreed to manufacture Bionpharma's Product for commercial sale. Id. The Agreement provides, among other things, that CoreRx must "accept all Firm Orders" made by Bionpharma with few exceptions, that only Bionpharma can cancel or defer orders, and — in a section entitled "Supply Interruption" — that "[i]f CoreRx is unable to supply any Product ordered by [Bionpharma] . . . , then CoreRx shall use Commercially Reasonable Efforts to remedy the problem or secure an alternative source of supply within a reasonable time." Id. at *2. The Agreement also provides that Bionpharma promises to indemnify CoreRx for any intellectual property infringement claims that might be brought against CoreRx for manufacturing Bionpharma's Product. Id. The Agreement provides that it would be "in full force and effect for a period of five (5) years from the commercialization of the last Product." Id.

Since the time that this Agreement was signed, Azurity has become CoreRx's sister company. See Compl. ¶ 23, ECF No. 1. The

companies' boards share a number of members, and the companies are owned by the same entity. Id.

On November 19, 2021, CoreRx notified Bionpharma that, "as of December 1, 2021, CoreRx will be unable to supply enalapril maleate for [Bionpharma's] Epaned product." Opinion & Order, 2022 WL 246742, at *3. After a brief, unsuccessful attempt by Bionpharma and CoreRx to resolve the matter amicably, id., Bionpharma brought this action on December 13, 2021, ECF No. 1. On the same day, Bionpharma moved for a preliminary injunction, ECF No. 8, which the Court granted on January 27, 2022. See Opinion & Order, 2022 WL 246742; see also ECF No. 79.

On February 2, 2022, Azurity moved to intervene in this action for the limited purpose of appealing the Opinion & Order.[1] ECF No. 66. On February 7, 2022, CoreRx moved to stay the preliminary injunction and to require Bionpharma to post security to maintain the injunction. ECF No. 82. The parties agreed to expedite briefing on both motions. ECF Nos. 81, 86. On February 22, 2022, CoreRx filed a notice of interlocutory appeal from the Opinion & Order. ECF No. 103.

CoreRx's first shipment of the Product under the preliminary injunction is due on March 4, 2022. See ECF No. 79.

[1] Azurity also sought to intervene for the purpose of moving the Court to reconsider its Opinion & Order, ECF No. 66, but Azurity has since withdrawn this portion of its motion, ECF Nos. 87, 104.

II.

A. Motion to Stay

CoreRx first moves to stay the preliminary injunction pending appeal. Alternatively, CoreRx seeks a limited interim stay to allow the court of appeals to consider whether a stay is warranted.

Under Federal Rule of Civil Procedure 62(c), the district court has the discretion to issue a stay pending appeal. There are four relevant factors to consider: (1) whether the movant will suffer irreparable injury absent a stay; (2) whether another party will suffer substantial injury if a stay is issued; (3) whether the movant has demonstrated a substantial possibility of success on the merits; and (4) the public interests that may be affected. See Hirschfeld v. Bd. of Elections in City of N.Y., 984 F.2d 35, 39 (2d Cir. 1993).[2] The movant bears the "heavy" burden of establishing that these factors weigh in its favor. See Barcia v. Sitkin, No. 79-cv-831, 2004 WL 691390, at *1 (S.D.N.Y. Mar. 31, 2004); see also D'Amico Dry D.A.C. v. Primera Mar. (Hellas) Ltd., 431 F. Supp. 3d 317, 319 (S.D.N.Y. 2019). In this case, these factors weigh strongly against granting a stay.

[2] Unless otherwise noted, this Memorandum Opinion and Order omits all alterations, citations, footnotes, and internal quotation marks in quoted text.

1.

The first factor, irreparable injury, requires an injury that is actual and imminent, not remote or speculative. Nat. Res. Def. Council, Inc. v. FDA, 884 F. Supp. 2d 108, 123 (S.D.N.Y. 2012). In favor of its motion for a stay, CoreRx argues that it "actually will suffer irreparable harm" if a stay is not granted, because enforcing the preliminary injunction will "expose CoreRx to liability for damages to Azurity in the eight or nine figures — enough to wipe CoreRx, which lacks assets sufficient to satisfy such a judgment, completely out of business," and "force CoreRx's hand in laying off over 200 workers currently employed in its factories." Def.'s Mem. in Supp. of Stay 14-15, ECF No. 84 ("Stay Mem."). But this claimed harm is speculative and remote. As Bionpharma rightly points out, CoreRx's claimed harm would follow "only from a chain of speculative future events": Azurity must sue CoreRx for patent infringement, the patents must be adjudged valid and infringed, CoreRx's defenses must fail, enhanced damages must be awarded, and Bionpharma must fail to indemnify CoreRx in violation of the Agreement. Pl.'s Opp. to Mot. to Stay 12, ECF No. 94 ("Stay Opp."). Even accepting Azurity's self-serving representation that it will sue its sister company for patent infringement as a result of this limited court order, CoreRx's claimed harm requires a series of completely speculative events to occur for

which there is no showing of likelihood. Indeed, CoreRx has not even attempted to prove that it is likely to lose a suit for patent infringement by Azurity.

Moreover, it is well established that "quantifiable money damages cannot be deemed irreparable harm." Harris v. Butler, 961 F. Supp. 61, 63 (S.D.N.Y. 1997). Unlike Bionpharma on the underlying motion, CoreRx complains about possible monetary damages from losing a patent infringement lawsuit, and does not allege that any reputational or other nonquantifiable harm will follow from the enforcement of its contractual duties. Nor has CoreRx made the "strong showing" necessary to show that economic loss would damage CoreRx's business irreparably. See D'Amico Dry, 431 F. Supp. 3d at 319 (quoting RxUSA Wholesale, Inc. v. Dep't of Health & Human Servs., 467 F. Supp. 2d 285, 301 (E.D.N.Y. 2006), aff'd sub nom. Dep't of Health & Human Servs., U.S. Food & Drug Admin. v. RxUSA Wholesale, Inc., 285 F. App'x 809 (2d Cir. 2008)). The first factor therefore weighs against CoreRx.

2.

The second factor, whether another party will suffer substantial injury if a stay is issued, also weighs against CoreRx. As the Court explained in its Opinion & Order, Bionpharma has made a strong showing of irreparable harm. CoreRx has provided no evidence to substantiate its claim that

Bionpharma will suffer "no material harm" if a stay is granted, or that Bionpharma's harm is compensable. See Stay Mem. 16. The Court continues to be persuaded that Bionpharma's inability to fulfil orders for its Product that it is under contractual obligation to supply, and its being forced to decline new orders, as a result of CoreRx's breach will result in substantial injury to Bionpharma's reputation and goodwill, and that this is cognizable harm in this circuit. CoreRx's attempt to distinguish this case from cases in this circuit finding irreparable harm based on similar risks of reputational damage is as unavailing here as it was on the underlying motion. The second factor therefore favors denying CoreRx's request for a stay.

3.

The third factor, likelihood of success on the merits, also strongly favors denying CoreRx's motion for a stay. For the reasons the Court outlined in its Opinion & Order, CoreRx is unlikely to succeed on the merits of its appeal. First, CoreRx is highly unlikely to succeed in demonstrating that the Court abused its discretion in finding that Bionpharma has a strong likelihood of success on the merits. As the Court explained, Bionpharma has adequately demonstrated that it is likely to succeed on its breach-of-contract claim against CoreRx. CoreRx's repeated arguments that no such claim lies because the parties'

Agreement is "preempted by federal patent laws" as indicated in Lear v. Adkins, 395 U.S. 653 (1969), and its progeny, or because the Agreement is "unenforceable under New York law on grounds of illegality" are unsubstantiated and are unavailing on the merits. See Opinion & Order, 2022 WL 246742, at *6-7. CoreRx does not attempt to allege that it did not breach its contract with Bionpharma. Rather, it argues only that its unsubstantiated fear of subjecting itself to a patent infringement suit is a basis to breach its contractual obligations — a proposition for which it admittedly has no support. Second, CoreRx is equally unlikely to succeed in demonstrating that the Court abused its discretion in finding that Bionpharma demonstrated irreparable harm. CoreRx's continued attempts to show that Bionpharma will suffer no irreparable harm absent an injunction are unpersuasive. Like the first two factors, the third factor weighs heavily against CoreRx.

4.

Finally, CoreRx fails to show that the public interest weighs in favor of granting a stay. As the Court explained in its Opinion & Order, if Bionpharma's Product were to be taken off the market, children — Bionpharma's primary user — and their parents would suffer. This harm is serious and tangible. This harm is also not minimized by CoreRx's claim that other generic versions of Epaned are now or will be on the market. Even

assuming that such generic versions are or will be available to patients and covered by their insurance, "forcing families to go through the burden of switching medications for their children does not serve the public interest." Opinion & Order, 2022 WL 246742, at *8.

On the other side of the ledger is CoreRx's repeated claim that it will lose Azurity's promised litigation and be forced into bankruptcy. These claims are wholly speculative and unproven. The fourth and final factor therefore weighs against CoreRx.

For the foregoing reasons, CoreRx's motion for a stay is **denied**. However, in deference to the court of appeals, CoreRx's alternative request that the Court temporarily stay the preliminary injunction is **granted**. The preliminary injunction requiring CoreRx to deliver a shipment of the Product to Bionpharma by March 4, 2022 is stayed until **March 2, 2022** to allow CoreRx to seek a stay from the court of appeals, and to allow the court of appeals to decide that request. But CoreRx is cautioned that this interim stay does not stay CoreRx's obligation to continue the preparation necessary to deliver the Product on March 4, 2022.

B. Motion to Set Security

CoreRx also moves to require Bionpharma to post security to maintain the preliminary injunction.

Federal Rule of Civil Procedure 65(c) provides that "[t]he court may issue a preliminary injunction . . . only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." As the court of appeals has explained, the bond requirement "serves a number of functions," including "assur[ing] the enjoined party that it may readily collect damages from the funds posted in the event that it was wrongfully enjoined, and that it may do so without further litigation and without regard to the possible insolvency of the plaintiff," and "provid[ing] the plaintiff with notice of the maximum extent of its potential liability." Nokia Corp. v. InterDigital, Inc., 645 F.3d 553, 557 (2d Cir. 2011). But the district court "has wide discretion to set the amount of a bond, and even to dispense with the bond requirement where there has been no proof of likelihood of harm, or where the injunctive order was issued to aid and preserve the court's jurisdiction over the subject matter involved." Doctor's Assocs., Inc. v. Distajo, 107 F.3d 126, 136 (2d Cir. 1997).

In this case, as is traditional, cf. Marro v. K-III Commc'ns Corp., 943 F. Supp. 247, 254 (E.D.N.Y. 1996) (denying bond under the "unusual and exigent circumstances presented"), a security bond is warranted, and CoreRx's motion to set security is **granted**. However, far from the multi-million-dollar figure

that CoreRx proposes, the Court agrees with Bionpharma that a $200,000 bond is sufficient in this case. As Bionpharma explains, this figure is calculated "based on the quantity of bottles to be delivered times the transfer price sought by CoreRx," Stay Opp. 19, and is therefore equivalent to "security only for those damages, if any, that might be proximately caused by the wrongful issuance of an injunction." Time Warner Cable, Inc. v. DIRECTV, Inc., No. 06-cv-14245, 2007 WL 1296205, at *2 (S.D.N.Y. May 2, 2007). Bionpharma should file its bond by **March 3, 2022.**

C. Motion to Intervene

Next, Azurity moves to intervene in this action for the limited purpose of appealing the Opinion & Order. Azurity argues that it should be entitled to intervene as a matter of right under Federal Rule of Civil Procedure 24(a), or, in the alternative, argues that the Court should allow Azurity to intervene permissively under Federal Rule of Civil Procedure 24(b).

Federal Rule of Civil Procedure 24(a)(2) provides for intervention as of right to any party who can: "(1) file a timely motion; (2) show an interest in the litigation; (3) show that its interest may be impaired by the disposition of the action; and (4) show that its interest is not adequately protected by the parties to the action." D'Amato v. Deutsche

Bank, 236 F.3d 78, 84 (2d Cir. 2001). The court of appeals has instructed that "a failure to satisfy any one of these four requirements is a sufficient ground to deny the application." Floyd v. City of New York, 770 F.3d 1051, 1057 (2d Cir. 2014). Separately, a movant may seek permissive intervention pursuant to Federal Rule of Civil Procedure 24(b). Under that Rule, "the court may permit anyone to intervene who . . . has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). Although permissive intervention is left to the discretion of the district court, courts consider "substantially the same factors whether the claim for intervention is 'of right' under [Rule 24(a)(2)], or 'permissive' under [Rule 24(b)(1)(B)]." R Best Produce, Inc. v. Shulman-Rabin Mktg. Corp., 467 F.3d 238, 240 (2d Cir. 2006). When considering a request for permissive intervention, however, the central factor is "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3); see United States v. N.Y.C. Hous. Auth., 326 F.R.D. 411, 418 (S.D.N.Y. 2018).

In this case, Azurity may not intervene as of right. It is true that Azurity's motion is timely because Azurity has sought to intervene "prior to any significant substantive motions" and less than two months after Bionpharma brought this action. See Bldg. & Realty Inst. of Westchester & Putnam Ctys., Inc. v. New

York, No. 19-cv-11285, 2020 WL 5667181, at *4 (S.D.N.Y. Sept. 23, 2020). Additionally, the Court will "not need to substantially extend any preexisting deadlines or reschedule any proceedings to accommodate the intervenor[]." See id. It is also true that Azurity adequately has shown an interest in the litigation that may be impaired in the disposition of this action. At the very least, Azurity has an economic interest in this case given its indemnity obligation to CoreRx for liability to Bionpharma in this action. See, e.g., Golden Ins. Co. v. PCF State Restorations, Inc., No. 17-cv-5390, 2018 WL 10593630, at *4-5 (S.D.N.Y. May 11, 2018).

However, Azurity has not shown that its interest is not adequately protected by CoreRx. "[W]hile the burden to demonstrate inadequacy of representation is generally speaking minimal, the Second Circuit has demanded a more rigorous showing of inadequacy in cases where the putative intervenor and a named party have the same ultimate objective." Bldg. & Realty Inst., 2020 WL 5667181, at *5. In such a situation, there is a "presumption of adequacy." Id.

In this case, both Azurity and CoreRx share the common objective of reversing the preliminary injunction so that CoreRx can continue to refuse to produce the Product to Bionpharma. Azurity has produced no evidence to show that CoreRx's representation is inadequate. While Azurity may take issue with

some of CoreRx's strategy in this action, "representation is not inadequate simply because they have different ideas about how best to achieve [their] goals." United States v. City of New York, 198 F.3d 360, 367 (2d Cir. 1999). Further, the fact that Azurity thinks it can better protect its own legal interests "fall[s] short of establishing that [CoreRx] will not vigorously [defend] this action and adequately [protect] the identical objectives of both" Azurity and CoreRx. See Bldg. & Realty Inst., 2020 WL 5667181, at *5. Nor is there any evidence whatsoever that Bionpharma and CoreRx are colluding, or of nonfeasance or incompetence on the part of CoreRx. See id. Accordingly, Azurity has failed to demonstrate that its interests are inadequately protected by CoreRx, and Azurity's motion to intervene as of right is **denied**.

Nevertheless, permissive intervention is warranted in this case. The test under Federal Rule of Procedure 24(b) is a "flexible and discretionary one." Id. at *6. Indeed, "[e]ven if intervention of right is unavailable, a court may still permit a party to intervene if the party has a claim or defense that shares with the main action a common question of law or fact." N.Y.C. Hous. Auth., 326 F.R.D. at 418. As stated, whether granting permissive intervention will unduly delay or prejudice the adjudication of the rights of the existing parties is the "the principal guide in deciding whether to grant permissive

intervention." Id. "[O]ther considerations include whether the applicant will benefit by intervention, the nature and extent of the intervenor['s] interests, whether [the intervenor's] interests are adequately represented by the other parties, and whether [the party] seeking intervention will significantly contribute to full development of the underlying factual issues in the suit and to the just and equitable adjudication of the legal issues present." Id.

Based on the facts of this case, the Court elects to exercise its "informed discretion" to grant permissive intervention for the limited purpose of appealing this Court's entry of a preliminary injunction. See id. "[W]hile existing adequate representation may militate against allowing permissive intervention, such intervention may still be appropriate," where, as here, "the addition of the intervenors will assist in the just and equitable adjudication of any of the issues between the parties." Id. Limited intervention by Azurity will provide the court of appeals with a "fuller picture" to evaluate whether this Court abused its discretion in granting Bionpharma's motion for a preliminary injunction. See id. at 419. Accordingly, Azurity's alternative request for permissive intervention is **granted.**

D. Motion to Supplement the Record

Finally, Azurity moves to supplement the record with (1) the settlement agreement between it and CoreRx, and (2) the papers filed in connection with Azurity's motion to intervene, including a declaration by Eli B. Richlin, counsel for Azurity, and a declaration by Amit M. Patel, Chief Executive Officer for Azurity.

Under Federal Rule of Appellate Procedure 10(e), the district court may supplement the record "[i]f anything material to either party is omitted from or misstated in the record by error or accident." Fed. R. App. P. 10(e)(2)(B).

In this case, neither supplement is necessary. First, the gist of the settlement agreement was explained to the Court prior to the issuance of the Opinion & Order. In any event, the settlement agreement is already in the record as a result of the stipulation and order between Bionpharma and CoreRx dated February 10, 2022. ECF No. 89. Accordingly, Azurity's motion to supplement the record with the settlement agreement is **denied** as moot.

Second, Azurity's papers in connection with this motion are not necessary to correct the record, and it would be unfair to Bionpharma to include these papers in the record because it has not had an adequate time to respond to them. The papers submitted by Azurity were not a basis for granting the motion

for a preliminary injunction, and Azurity has withdrawn the request for reconsideration. Azurity's motion to supplement the record with these papers is therefore also **denied.**

CONCLUSION

The Court has considered all of the arguments raised by the parties. To the extent not specifically addressed, the arguments are either moot or without merit.

For the foregoing reasons, (1) CoreRx's motion for a stay is **denied**, but its alternative motion for an interim stay is **granted** until **March 2, 2022** to allow CoreRx to seek a stay from the court of appeals, and to allow the court of appeals to decide such a request. CoreRx should continue to prepare for its shipment to Bionpharma due March 4, 2022. (2) CoreRx's motion requiring Bionpharma to post a security bond is **granted.** Bionpharma shall file its bond in the amount of $200,000.00 with the Clerk of Court by **March 3, 2022.** (3) Azurity's motion to intervene as a matter of right is **denied**, but its alternative motion to intervene permissively is **granted.** (4) Azurity's motion to supplement the record is **denied.**

The Clerk is requested to close ECF Nos. 66 and 82.

SO ORDERED.

Dated: New York, New York
February 24, 2022

John G. Koeltl
United States District Judge